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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/890,490	07/09/97	ANTHONY FENN	R F3141(V)

EXAMINER	
NESSLER,C	
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IM52/0411

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/890,490	Applicant(s) Fenn et al
	Examiner Cynthia L. Nessler	Group Art Unit 1761

☒ Responsive to communication(s) filed on *Feb 1, 2001*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *5 and 6* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *5 and 6* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The rejection of the claims below under 35 U.S.C. 102(f) is maintained because the present action does not contain a definite statement by counsel that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now recite the term "brittle". In determining what the applicants mean by "brittle", see the paragraph appearing at the bottom of page 15 of the specification. In order to obtain a measure of brittleness, the applicants compared the present product with a control sample. The paragraph states that for the control sample a thickness of 966 metres (or 0.6 miles) was necessary to obtain a brittle layer, while for the present invention, brittleness was found at a thickness of 3 mm. Therefore, for brittleness, the control sample required a thickness of over a half a mile. This required thickness is not understood. Clarification is requested.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Clemmings et al or Warren et al in view of WO 92/22581, applicants' admission, and the Griffith et al article "Antifreeze Proteins and Their Use in Frozen Foods".

Either Clemmings et al or Warren et al disclose the use of antifreeze peptides in frozen confectionary products and mixes such as ice cream. The claims differ in the recitation of the aspect ratio. As admitted by the applicants in the first paragraph of page 2 of the specification, antifreeze peptides are known for their ability to influence the shape of ice crystals (according to WO 92/22581). The aspect ratio is a measurement of the shape of a particle, such as a crystal (typically a length ratio of the major to minor axis of the crystal). The aspect ratio (shape) of the crystals is therefore considered to be a result effective variable, dependent upon, for example, the desired texture and mouthfeel of the final product, absent a showing of unexpected results. It would have been obvious to utilize the antifreeze peptides of either Clemmings et al or Warren et al in the frozen confectionary products of either primary reference to influence the shape of the ice crystals formed in order to provide a desired aspect ratio and a desired texture.

Note in lines 11-22 of page 21 of WO 92/22581 that low concentrations of antifreeze proteins preferentially inhibit the a-axis growth, while at high concentrations, the crystals grow predominantly along the c-axis to form hexagonal bipyrimids. Therefore, WO 92/22581 teaches that the concentration of the antifreeze proteins influences the shape (i.e., the aspect ratio) of the ice crystals formed. Also note that WO 92/22581 teaches the application of the invention to ice cream and other frozen foods in lines 20-30 of page 30. It therefore would have been obvious to

alter the conditions by controlling the concentration antifreeze proteins of either Clemmings et al or Warren et al to influence the shape of the ice crystals as taught by WO 92/22581.

While Clemmings et al teach particle sizes averaging 27 microns in line 56 of column 4, the Griffiths et al article teach, on page 391 in the first paragraph of the section entitled "Addition of Antifreeze Proteins Directly to Foods", that ice cream can be frozen with higher concentrations of antifreeze proteins to minimize the size of the ice crystals. Therefore the ice crystal size is a result effective variable, dependent upon, for example, the antifreeze protein concentration and the desired texture in the end product. See also the penultimate paragraph of page 387 of the Griffiths et al article, teaching that the inhibition of ice recrystallization (i.e., control of the ice crystal size) can be an important factor in determining the texture of ice cream. Griffiths also teaches. in the "Conclusions" section found on page 393, that the concentrations and types of AFP's in frozen foods are selected, depending upon, for example, the range of temperatures used in processing, or the desired texture (at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained). Therefore, the type and concentration of the AFP's are result effective variables which influence the shape (i.e., aspect ratio) of the crystals as well as the texture of the final ice cream product. Therefore, the ice crystal size as well as the type and concentration of antifreeze proteins in the frozen confection is a result effective variable for the reasons discussed above. Note in any event that Clemmings teaches concentrations of antifreeze proteins which overlap the recited range in liens 47-50 of column 2.

Regarding the recitation of the type of antifreeze protein (Type III HPLC 12), the Griffiths et al article teaches the use of not only Type III but also that the type of antifreeze protein is selected depending upon the range of temperatures used in processing or the desired texture in the end product (see the discussion immediately above). Therefore Griffiths teaches that the selection of the type is a result effective variable.

Furthermore, the applicants admit that the aspect ratio is a result effective variable in lines 34-37 of page 5 of the present specification, stating that "it is well within the ability of the skilled person to choose those conditions such that the aspect ratio of the ice crystals falls within the desired range" .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 5 and 6 are rejected under 35 U.S.C. 102(f) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 97/02343. Claims 5 and 6 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. WO 97/02343, filed by an entirely different inventive entity (no common inventors listed) teach the preferred embodiment of the recited antifreeze protein type in ice cream on page 12. The recited properties such as aspect ratio and particle size are inherent, or if not fully inherent, are result effective

variables dependent upon the desired texture of the final ice cream product absent a showing of unexpected results as discussed above.

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tripp et al.

Tripp et al teach the recited antifreeze protein in ice cream in Example 4 (columns 16-18). The recited properties such as aspect ratio and particle size are inherent, or if not fully inherent, are result effective variables dependent upon the desired texture of the final ice cream product absent a showing of unexpected results as discussed above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6096867 in view of Griffith et al article "Antifreeze Proteins and Their Use in Frozen Foods".

The patent claims recite frozen confectionery products containing AFP's derived from plants such as the carrot, which inherently provides a brittle texture, depending upon the concentration of the AFP in the ice confection. The claims differ in the recitations of the concentration of AFP and also of the type. Griffiths teaches in the "Conclusions" section found on page 393, that the concentrations and types of AFP's in frozen foods are selected, depending upon, for example, the range of temperatures used in processing, or the desired texture (at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained). Therefore, the type and concentration of the AFP's are result effective variables which influence the shape (i.e., aspect ratio) of the crystals as well as the texture of the final ice cream product. Regarding the recitation of the type of antifreeze protein (Type III HPLC 12), the Griffiths et al article teaches the use of not only Type III but also that the type of antifreeze protein is selected depending upon the range of temperatures used in processing or the desired texture in the end product (see the discussion immediately above). Therefore Griffiths teaches that the selection of the type is a result effective variable. When a parameter has been shown to be result effective, a prima facie case of obviousness has been established, and the burden passes to the applicants to show unexpected results. See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

Claims 5 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6156880 in view of Griffith et al article "Antifreeze Proteins and Their Use in Frozen Foods".

The patent claims differ in the recitation of the type of AFP. Griffiths teaches in the "Conclusions" section found on page 393, that the concentrations and types of AFP's in frozen foods are selected, depending upon, for example, the range of temperatures used in processing, or the desired texture (at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained). Therefore, the type and concentration of the AFP's are result effective variables which influence the shape (i.e., aspect ratio) of the crystals as well as the texture of the final ice cream product. Regarding the recitation of the type of antifreeze protein (Type III HPLC 12), the Griffiths et al article teaches the use of not only Type III but also that the type of antifreeze protein is selected depending upon the range of temperatures used in processing or the desired texture in the end product (see the discussion immediately above). Therefore Griffiths teaches that the selection of the type is a result effective variable. When a parameter has been shown to be result effective, a prima facie case of obviousness has been established, and the burden passes to the applicants to show unexpected results. See *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Arai et al teach frozen foods containing antifreeze proteins. Arai teaches concentrations within the presently recited range in line 20 of column 3. Note particularly lines 23-26 of column 3 of Arai, which teach "an amount of the antifreezing agent varies depending upon the desired storage temperature, kinds of product to be frozen, a rate of cooling, and the like". Therefore, Arai teaches that the amount of antifreezing agent present is a result effective variable.

Lee teach, in lines 37-41 of column 7, that the amount of material to be added to assist in ice nucleation according to the present invention will depend upon the nature of the material used and in particular on the temperature at which it will induce nucleation in supercooled water. Ice nucleating proteins are disclosed.

Fletcher et al teach that the number of fish antifreeze-expressing microorganisms added to the food product will depend on the properties of the microorganisms and of the food.

Arbuckle, "Ice Cream", third edition, on page 323, expressly teaches that the texture of ice cream is dependent upon variables such as the shape of the ice crystals (see the first and second paragraphs under the heading "Body and Texture Defects"). In the paragraph bridging pages 325 and 326, Arbuckle teaches that the texture also depends on the size of the crystals. In the first two lines of page 330, Arbuckle teaches that rate of freezing and hardening affect texture; and that fast freezing produces small ice crystals.

Perry's Chemical Engineering Handbook, sixth edition, teaches that the "aspect ratio" is used to describe the shape of a particle, and that the particle shape can be related to functional properties of the particles.

Gordon et al, in column 11, lines 10-40, teaches textbook information regarding the aspect ratio measurement. Lines 47-48 of column 3 of Nordhauser et al teach that the aspect ratio has historically been used to demonstrate particle shape.

Applicant's arguments filed February 1, 2001 have been fully considered but they are not persuasive.

The applicants argue that even though WO 97/02343 teaches that AFP's influence the shape of the ice crystals, even though Arbuckle teaches that the texture of the ice cream is dependent upon the shape of the ice crystals, and even though the "Conclusions" section of the Griffiths et al article teaches or fairly implies that the texture of the ice cream is dependent upon the concentration and the type of AFP, i.e., at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained (as discussed above), WO 97/02343 does not teach how to obtain a brittle texture. However, the type and concentration of the AFP is a result effective variable, dependent on the desired texture, as discussed above. Therefore the texture is similarly dependent upon the type and concentration of the AFP. The brittleness of the structure is not unexpected when using AFP, since at higher concentrations, spicular ice formation results as taught by Griffith. Similarly, WO 97/02343

teaches that at higher concentrations, the crystals grow predominantly along the c-axis. Therefore, the degree of brittleness depends upon the AFP concentration as taught by Griffith and WO 97/02343.

Regarding the type (III) of AFP, the Griffiths et al article teaches the use of not only Type III but also that the type of antifreeze protein is selected depending upon the range of temperatures used in processing or the desired texture in the end product (see the discussion immediately above). Therefore Griffiths teaches that the selection of the type is a result effective variable. When a parameter has been shown to be result effective, a prima facie case of obviousness has been established, and the burden passes to the applicants to show unexpected results. See *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980).

Any concerning this communication or earlier communications from the examiner should be directed to Cynthia L. Nessler whose telephone number is (703) 308-3843.

cn

April 8, 2001

Cynthia L. Nessler

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